FDA approves Roche's OCREVUS® (ocrelizumab) shorter 2-hour infusion for relapsing and primary progressive multiple sclerosis

- **Approval based on data from the randomised, double-blind ENSEMBLE PLUS study, showing consistent safety to the conventional OCREVUS dosing regimen**
- **Shorter infusion time will further improve the twice-yearly treatment experience for OCREVUS, the only B-cell therapy for relapsing and primary progressive MS with a twice-yearly dosing schedule**

Basel, 14 December 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has approved a shorter two-hour infusion time for OCREVUS® (ocrelizumab), dosed twice-yearly for those living with relapsing or primary progressive multiple sclerosis (MS) who have not experienced any prior serious infusion reactions (IRs). The approval was based on data from the randomised, double-blind ENSEMBLE PLUS study.

"More than 170,000 people with MS have been treated with OCREVUS - the only approved B-cell therapy with a twice-yearly dosing schedule - and it is the most prescribed MS medicine in the U.S.," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "We constantly strive to improve the experience that patients and their physicians have with our medicines, and we believe people with relapsing and primary progressive MS will find the shorter two-hour OCREVUS infusion time to be more convenient."

The ENSEMBLE PLUS study showed similar frequency and severity of IRs for a two-hour OCREVUS infusion time vs. the previously approved 3.5-hour time in patients with relapsing-remitting MS (RRMS). The first dose was administered per the approved dosing schedule (two 300 mg intravenous [IV] infusions separated by two weeks) and the second or later doses (600 mg IV infusion) were administered over a shorter, two-hour time.

The primary endpoint of this study was the proportion of patients with IRs following the first randomised 600 mg infusion (frequency/severity assessed during and 24-hours post infusion). The frequency of IRs was comparable between those who received the two-hour infusion (24.6%) and those who received the 3.5-hour infusion (23.1%). The majority of IRs were mild or moderate, and more than 98% resolved in both groups without complication. No IRs were life-threatening, serious or fatal. No patients discontinued the study due to an IR and no new safety signals were detected.

The European Medicines Agency (EMA) approved the two-hour infusion time in May of 2020 based on a positive opinion from the Committee for Medicinal Products for Human Use (CHMP).

OCREVUS has twice-yearly (six-monthly) dosing and is the first and only therapy approved for relapsing

multiple sclerosis (RMS) (including RRMS and active, or relapsing, secondary progressive MS [SPMS], in addition to clinically isolated syndrome [CIS] in the U.S.) and primary progressive MS (PPMS). OCREVUS is approved in 94 countries across North America, South America, the Middle East, Europe, as well as in Australia.

About OCREVUS® (ocrelizumab)
OCREVUS is a humanised monoclonal antibody designed to target CD20-positive B cells, a specific type of immune cell thought to be a key contributor to myelin (nerve cell insulation and support) and axonal (nerve cell) damage. This nerve cell damage can lead to disability in people with MS. Based on preclinical studies, OCREVUS binds to CD20 cell surface proteins expressed on certain B cells, but not on stem cells or plasma cells, suggesting that important functions of the immune system may be preserved. OCREVUS is administered by intravenous infusion every six months. The initial dose is given as two 300 mg infusions given two weeks apart. Subsequent doses are given as single 600 mg infusions.

About Roche in multiple sclerosis
Roche is following the science in an effort to ultimately stop disease progression and preserve function in people living with multiple sclerosis (MS). As a company, we continue to advance the clinical understanding of MS and progression with the aim of bringing the most benefit to people living with MS.

About Roche in neuroscience
Neuroscience is a major focus of research and development at Roche. Our goal is to pursue groundbreaking science to develop new treatments that help improve the lives of people with chronic and potentially devastating diseases.

Roche is investigating more than a dozen medicines for neurological disorders, including multiple sclerosis, neuromyelitis optica spectrum disorder, Alzheimer's disease, Huntington's disease, Parkinson's disease, Duchenne's muscular dystrophy and autism spectrum disorder. Together with our partners, we are committed to pushing the boundaries of scientific understanding to solve some of the most difficult challenges in neuroscience today.

About Roche
Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology,

infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the twelfth consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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